Press Release

Sensorion Completes Patient Enrollment of the Second Cohort in Audiogene Phase 1/2 Gene Therapy Clinical Trial

Montpellier, July 29, 2025, 7.30 am CET – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company specializing in the development of novel therapies to restore, treat and prevent hearing loss disorders, today announced the completion of patient enrollment in the second cohort of its Phase 1/2 Audiogene clinical trial evaluating SENS-501, the Company's gene therapy candidate being developed to treat a specific form of congenital deafness linked to mutations in the OTOF (otoferlin) gene.

Recruitment of the second cohort, composed of three patients aged between 6 and 31 months, was recently completed with the injection of the third patient**.** Patients in this second cohort were administered, unilaterally, a dose of d4.5^{E}11 vg/vector/ear of SENS-501 which was higher than the dose in the 1st cohort (1.5^{E}11 vg/vector/ear). For all patients treated in the first and second cohorts, the surgical procedure was well tolerated: the intra-cochlear administration of the gene therapy product was uneventful. No serious adverse events and no serious side effects were reported. Early signs of hearing improvement have been observed in Patient 3, aged 11 months at the time of injection, three months after receiving the low dose.

Nawal Ouzren, Chief Executive Officer of Sensorion, commented: *"The completion of patient enrollment in the second cohort in Audiogene is an important milestone as it enables us to attest to the safety of the surgical approach, as no serious adverse events have been observed in all six patients injected, and of the good tolerability of SENS-501 to date. I look forward to advancing this innovative and unique program to its next steps, notably with the planned Data Monitoring Committee meeting, and to providing an update as soon as the data have sufficiently matured. On behalf of my colleagues, I would like to extend gratitude to the patients' families for their trust, as well as all the healthcare professionals involved in this clinical trial."*

Professor Natalie Loundon, M.D., Director of the Center for Research in Pediatric Audiology, Pediatric Otolaryngologist and Head and Neck Surgeon, Necker Enfants Malades, AP-HP, in Paris, France, Principal Investigator of the Audiogene clinical study, added: *"I am thrilled we have successfully completed the patient enrollment of the second Cohort in Audiogene's Phase 1/2 gene therapy trial. The good tolerability of patients to SENS-501 so far and the preliminary positive data from the first cohort are very encouraging first steps for the continuation of this trial that has the potential to address a global significant unmet medical need. Once again, I would like to thank the patients' families for their trust."*

Audiogene (**ClinicalTrials.gov ID:** NCT06370351) is the first gene therapy clinical trial addressing a unique homogeneous population of infants and toddlers (aged 6 to 31 months and naive of cochlear implants at the time of the injection, as per study protocol). Audiogene's clinical trial design has been intended to assess SENS-501 gene therapy product's safety and tolerability as well as its capacity not only to restore hearing but also to allow the infants and toddlers to acquire and develop normal speech. Moreover, Audiogene aims to evaluate the usability, the clinical and the technical performances of the injection system in development.

About SENS-501

SENS-501 (OTOF-GT) is an innovative gene therapy program developed to treat a specific form of congenital deafness linked to mutations in the OTOF (otoferlin) gene. This gene plays a key role in the transmission of auditory signals between the hair cells of the inner ear and the auditory nerve. When this gene is defective, affected individuals are born with severe to profound hearing loss.
The aim of SENS-501 (OTOF-GT) is to restore hearing by introducing a functional copy of the OTOF gene directly into hair cells via viral vector technology (AAV). This therapy aims to restore the normal process of converting sound into electrical signals, enabling patients to regain their hearing ability. Currently in the clinical research phase, this gene therapy program represents significant hope for families affected by this rare form of genetic deafness. SENS-501 (OTOF-GT) embodies a commitment to scientific innovation in the field of hearing, with the potential to dramatically improve the quality of life of patients suffering from genetic deafness. This gene therapy for patients suffering from otoferlin deficiency has been developed in the framework of RHU AUDINNOVE, a consortium composed of Sensorion with the Necker Enfants Malades Hospital, the Institut Pasteur, and the Fondation pour l'Audition. The project is partially financed by the French National Research Agency, through the "investing for the future" program (ref: ANR-18-RHUS-0007). The OTOF gene targeted by the Audiogene trial was discovered in 1999 at the Institut Pasteur, by Prof. Christine Petit's team (Institut reConnect, Institut de l'Audition, Pasteur Institute), who also unraveled the pathophysiology of the corresponding deafness (DFNB9).

About the Audiogene Trial

Audiogene aims to evaluate the safety, tolerability and efficacy of intra-cochlear injection of SENS-501 for the treatment of OTOF gene-mediated hearing loss in infants and toddlers aged 6 to 31 months at the time of gene therapy treatment. By targeting the first years of life, when brain plasticity is optimal, the chances of these young children with pre-linguistic hearing loss acquiring normal speech and language are maximized. The study comprises two cohorts of two doses followed by an expansion cohort at the selected dose. While safety will be the primary endpoint of the first part of the dose escalation study, auditory brainstem response (ABR) will be the primary efficacy endpoint of the second part of the expansion. Audiogene will also evaluate the clinical safety, performance and ease-of-use of the delivery system developed by Sensorion.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat, and prevent hearing loss disorders, a significant global unmet medical need. Sensorion has built a unique R&D technology platform to expand its understanding of the pathophysiology and etiology of inner ear related diseases, enabling it to select the best targets and mechanisms of action for drug candidates.
It has two gene therapy programs aimed at correcting hereditary monogenic forms of deafness, developed in the framework of its broad strategic collaboration focused on the genetics of hearing with the Institut Pasteur. SENS-501 (OTOF-GT) currently being developed in a Phase 1/2 clinical trial, targets deafness caused by mutations of the gene encoding for otoferlin and GJB2-GT targets hearing loss related to mutations in GJB2 gene to potentially address important hearing loss segments in adults and children. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses.
Sensorion's portfolio also comprises programs of a clinical-stage small molecule, SENS-401 (Arazasetron), for the treatment and prevention of hearing loss disorders. Sensorion's small molecule progresses in a Phase 2 proof of concept clinical study of SENS-401 in Cisplatin-Induced Ototoxicity (CIO) for the preservation of residual hearing. Sensorion, with partner Cochlear Limited, completed in 2024 a Phase 2a study of SENS-401 for the residual hearing preservation in patients scheduled for cochlear implantation. A Phase 2 study of SENS-401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in January 2022.
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